RECEIVED
CATHY A. CATTERSON, CLERK
U.S. COURT OF APPEALS
APR 15 2005
FILED
DOCKETED
DATE INITIAL

Case No. 05-35264

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff/Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
Animal and Plant Health Inspection Service, *et al.*,
Defendants/Appellants.

On Appeal from the United States District Court for the District of Montana

---

BRIEF *AMICUS CURIAE* OF THE GOVERNMENT OF CANADA IN SUPPORT OF APPELLANTS AND IN SUPPORT OF REVERSAL OF THE DISTRICT COURT ORDER GRANTING A PRELIMINARY INJUNCTION

Maureen E. Mahoney
Cassandra Sturkie
LATHAM & WATKINS LLP
555 Eleventh Street, N.W., Suite 1000
Washington, DC 20004-1304
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
Email: maureen.mahoney@lw.com
Email: cassandra.sturkie@lw.com

Counsel for the Government of Canada

DATED: April 14, 2005

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

FEDERAL STATUTES

OTHER AUTHORITY

INTEREST OF THE *AMICUS CURIAE*

The United States District Court for the District of Montana granted Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America's ("R-CALF") application for a preliminary injunction to enjoin the implementation of the United States Department of Agriculture's ("USDA") Final Rule.[1] The district court's injunction improperly blocks the resumption of certain live cattle and edible bovine product imports from Canada into the United States – notably, live cattle under 30 months of age – without any scientific or legal justification. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, 2005 WL 525689, at *15 (D. Mont. Mar. 2, 2005) ("Opn."); *see also id.* at *9 (explaining that USDA has delayed the portion of the Rule applying to beef products from cattle 30 months of age or older).

---

[1] The Final Rule is entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Part III," 70 Fed. Reg. 460 (Jan. 4, 2005). *See* Administrative Record ("AR") 8043-8137A. The Final Rule places Canada in a "minimal risk" category and, on that basis, lifts prohibitions on the importation of certain ruminants and ruminant products from Canada that were imposed after Canada detected the first case of Bovine Spongiform Encephalopathy ("BSE") in 2003. AR8044-45. The beef products that are currently imported from Canada into the United States, discussed *infra*, are not at issue in this appeal, nor are the provisions of the Final Rule relating to other ruminants, such as sheep.

As explained in the accompanying motion which sets forth the authority to file this brief, the Government of Canada ("Canada") has a significant sovereign interest in ensuring that the public at home and abroad understands that it is safe to consume beef from Canadian cattle. The district court's decision seriously undermines that interest because it rests on the unfounded premise that Canadian cattle pose a threat to human and animal health. *See id.* at *15. For the reasons described below, the Secretary of Agriculture properly determined that Canada's program to minimize human and animal exposure to BSE in North America – which is indistinguishable from the United States' own BSE program – has virtually eliminated all health risks posed by this disease.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress adopted the Animal Health Protection Act to protect public health in a manner that does not needlessly burden foreign commerce. 7 U.S.C. § 8301(1)(A)-(E). The Act accordingly authorizes restrictions on the importation of Canadian cattle only "if the Secretary determines that the prohibition or restriction is necessary" to "prevent the introduction into or dissemination within the United States of any ... disease." 7 U.S.C. § 8303(a)(1). Applying this standard, the Secretary determined that continuing the temporary ban on the importation of cattle under 30 months would impermissibly eliminate vital trade in cattle with Canada because such a ban is *not* "necessary" to protect the health of

United States consumers of beef or to prevent transmission of BSE among cattle in North America. AR8095-96 (declining to make trade dependent on "zero risk"). The district court nevertheless disregarded the Secretary's expert judgment based on two speculative findings of potential harm that cannot withstand scrutiny.

First, the district court adopted R-CALF's scientifically untenable claim that the detection of a total of four cases of BSE in Canadian-born cattle (three in Canada and a fourth in the United States) – out of the Canadian national herd that numbered 6.7 million adult cattle in 2004 – makes it a "virtual certainty" that "Canadian cattle infected with BSE would be imported into the U.S." in the absence of a preliminary injunction. Opn., 2005 WL 525689, at *6.[2] *See* Memorandum of Points and Authorities in Support of Plaintiff's Application for a Preliminary Injunction, No. CV-05-06-BLG-RFC, at 12 (D. Mont. Feb. 1, 2005) ("R-CALF Br.") (same "virtual certainty"). But the facts of those cases are consistent with the Secretary's determination that there is no significant risk – let

---

[2] Canada confirmed the detection of two of these cases on January 2 and 11, 2005, respectively. *See* Canadian Food Inspection Agency ("CFIA") Questions and Answers Case #3 (hereafter "CFIA Questions and Answers Case #3"), at 1-2, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3queste.shtml (last viewed Apr. 13, 2005).

alone a "virtual certainty" – that Canadian cattle imported at less than 30 months of age would be infected with BSE.

The Secretary relied upon uncontroverted scientific evidence that BSE is neither contagious nor otherwise readily transmissible among cattle. The "only documented route" of transmission of BSE among cattle is through an animal's consumption of feed containing protein from ruminants infected with BSE – a practice prohibited throughout North America when both Canada and the United States implemented a ruminant-to-ruminant feed ban in 1997. AR8114. Furthermore, the incubation period for BSE in cattle normally ranges from four to five years (48-60 months), AR8058, but lower exposure levels to the disease result in longer incubation periods. AR8096-97; *see also* Government of Canada, "Technical Overview of BSE in Canada – March 2005" (hereafter "Canada Report") at 5, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.pdf (last viewed Apr. 14, 2005), *cited in* "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule, Part VII," 70 Fed. Reg. 18,252, 18255, 18258 (Apr. 8, 2005).[3] This has proven to

---

[3] This Court may consider the publications of the Canadian Government cited herein. USDA expressly relied on the Canada Report and other publications

be the case in Canadian-born cattle, in which all four animals infected with BSE were approximately six to eight years of age (ranging from 70 to 90 months); were born before or shortly after Canada implemented its feed ban in 1997; and were believed to have eaten BSE-contaminated feed. *See* AR8052-53; CFIA Questions and Answers Case #3, at 1-2. This evidence suggests that Canadian cattle much older than 30 months can be imported into the United States with little risk of introducing BSE. The Final Rule, however, conservatively requires all cattle imported from Canada to be slaughtered *before* they reach 30 months of age. AR8069. Thus, *none of the animals infected with BSE could have been imported into the United States* under the Rule, and there is simply no scientific basis to expect cattle born years after Canada's feed ban took effect, and slaughtered at less

---

of the Canadian Government in its Finding of No Significant Impact and Affirmation of the Final Rule. *See* 70 Fed. Reg. at 18,255, 18,258-59. Moreover, courts of appeals may take judicial notice of government reports not introduced in the district court. *United States v. Camp*, 723 F.2d 741, 743-44 & n.** (9th Cir. 1984); *see also* Fed. R. Evid. 201(f). Courts also rely on amicus briefs filed by foreign governments for information not contained in the record. *See, e.g., Barclays Bank PLC v. Franchise Tax Bd.*, 512 U.S. 298 (1994) (citing amicus brief filed by Canada); *Confederated Tribes & Bands of Yakama Indian Nation v. Baldridge*, 898 F. Supp. 1477, 1479 (W.D. Wash. 1995) (considering brief filed by Canada), *aff'd*, 91 F.3d 1366 (9th Cir. 1996). Nonetheless, if this Court determines that it should not consider the Canada publications cited herein, Canada respectfully asks this Court to disregard these limited references.

than 30 months of age, to be infected with BSE. AR8097; AR8329-31; AR8099; AR9961; *see also* Declaration of Lisa A. Ferguson ("Ferguson Dec.") ¶¶ 15-16, Exhibit 2 to Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction, No. CV-05-06-BLG-RFC (D. Mont. Feb. 22, 2005).

Second, the district court afforded no deference to the Secretary's determination that the risk to human health posed by these imports is "exceedingly low,"[4] finding instead that the importation of any cattle infected with BSE would place beef consumers in the United States at a "catastrophic risk of danger." Opn., 2005 WL 525689, at *6. The district court ignored extensive evidence in the record that human exposure to BSE from Canadian beef has been effectively eliminated through the low incidence rate of BSE in the Canadian herd and the removal of potentially infected tissues ("specified risk materials" or "SRMs") when cattle are slaughtered for human consumption.[5] The record establishes that

---

4 *See* Ferguson Dec. ¶ 9 (stating that "qualitative and quantitative evidence" demonstrates that any risk associated with imports under the Final Rule is "exceedingly low").

5 The BSE agent in cattle is not distributed throughout the bovine body and is absent from muscle tissue typically eaten by consumers as meat or beef products. Rather, the BSE agent is concentrated in SRMs, which consists of the brain, retinas, spinal cord, nerve cells closely attached to the head and vertebral column, tonsils, and a part of the small intestine known as the distal ileum. AR8078; AR9965; *see also* Canada Report at 8, 11.

the only human disease related to BSE in cattle is variant Creutzfeldt-Jakob Disease ("vCJD"); that a substantial species barrier hinders the transmission of the BSE agent from cattle to humans; and that the only known route of transmission of the BSE agent is through human consumption of infective tissue found in SRMs. Indeed, ***there has never been a single case of vCJD in the world linked to the consumption of beef from Canadian cattle***. *See* Canada Report at 6.

R-CALF accordingly did not demonstrate any likelihood of succeeding on its claim that the Final Rule is arbitrary and capricious, or that the preliminary injunction is necessary to prevent "the possibility of quintessential irreparable harm" to United States consumers (Opn., 2005 WL 525689, at *13). The injunction is based on unfounded fears at odds with the overwhelming historical facts and scientific evidence that USDA reaffirmed as recently as April 8, 2005, after extensively reviewing the two cases of BSE confirmed in January 2005 and determining that Canada's risk mitigation measures continue to be highly effective. *See* 70 Fed. Reg. at 18,255-56. The Government of Canada respectfully urges this Court to reverse the district court's order granting a preliminary injunction and permit the Final Rule to take effect. *See, e.g., Kootenai Tribe v. Veneman*, 313 F.3d 1094 (9th Cir. 2002) (reversing order granting preliminary injunction); *Caribbean Marine Servs. Co. v. Baldridge*, 844 F.2d 668, 674 (9th Cir. 1988) (reversing grant of preliminary injunction where plaintiff failed to

demonstrate "immediate threatened injury"); *Colorado River Indian Tribes v. Town of Parker*, 776 F.2d 846, 849-50 (9th Cir. 1985) (reversing grant of preliminary injunction because "theoretical harm" and "speculative injury" do not constitute irreparable injury).

ARGUMENT

I. CANADA'S BSE RISK MITIGATION MEASURES PROTECT HUMAN HEALTH AND QUALIFY CANADA AS A MINIMAL-RISK REGION

The district court rejected USDA's assessment of the impact of the Final Rule on human health. Opn., 2005 WL 525689, at *7. The district court instead inferred that the detection of four cases of BSE in Canadian-born cows poses a heightened risk of vCJD for United States consumers that justifies the preliminary injunction. *See id.* at *6 (stating that the Canadian imports put United States consumers at "a genuine risk of death"). The district court's *de novo* findings about the alleged threats to public health posed by the Final Rule lack any scientific basis and are at odds with the record supporting the Final Rule. *See, e.g.*, AR8095-96. Indeed, the district court's views are not even supported by R-CALF, which admitted to this Court in the related appeal that it "never argued that there was a great risk to human health from [the] resumed imports." R-CALF Answering Brief, Case No. 05-35214, at 44 (9th Cir. Mar. 29, 2005).

Moreover, the district court fundamentally mischaracterizes the effectiveness of the mitigation measures implemented by Canada and the United States to minimize human exposure to BSE and limit the potential for BSE to spread. Based on the scientific and other record evidence, USDA correctly determined that Canada's mitigation measures function effectively, in concert with equivalent safeguards operated by the United States, and that any risk of United States consumers contracting vCJD from beef from Canadian cattle is therefore extremely low. AR8049; AR8075; AR8089-90.

A. The Risk Of Humans Contracting vCJD From Canadian Beef Has Been Effectively Eliminated

The risk of United States consumers contracting vCJD from eating beef from Canadian cattle is extremely improbable even though BSE may not yet be completely eliminated from the Canadian cattle population. AR8089-90. BSE is exceedingly rare in Canada, and Canada has implemented a comprehensive BSE program that protects Canadian livestock and consumers of beef. *Id.*; AR8048. The district court could only find otherwise by ignoring historical facts and scientific evidence.

First, the court failed to acknowledge that ***there has never been a single case of vCJD*** linked to the consumption of beef from Canadian cattle. *See*

Canada Report at 6. Since 1996, when vCJD was first described as a new disease, Canada has exported approximately 4 million tons (U.S.) of beef products,[6] and Canadians have consumed approximately 70 pounds of Canadian beef per person each year without incident.[7] United States consumers are not somehow more likely than Canadians to contract vCJD from beef from Canadian cattle. Indeed, Americans have consumed substantial quantities of beef from Canadian cattle since 1996, except during a brief hiatus in mid-2003 when imports were halted following confirmation of the first case of BSE in a Canadian cow in May 2003. That consumption has likewise been without incident. Ending that hiatus in August 2003, the Secretary of Agriculture announced that imports of Canadian boneless beef from cattle under 30 months of age would resume under a permit process. The fact that it is safe for cattle under 30 months of age to be slaughtered in Canada and their boneless meat shipped to the United States is itself compelling proof that it is safe for these same cattle to cross the border for slaughter here.

The experience of other countries reinforces the expectation of continued human safety. To put into context the low risk of contracting vCJD

---

6 *See* http://www.cbef.com/PDF/Stats_1990-2010.pdf (last viewed Apr. 13, 2005) (total exports).

7 http://estat.statcan.ca (Table 002-0011).

from Canadian beef, the annual incidence rate of BSE in the United Kingdom during the height of its epidemic was 7,500 cases per million adult cattle (based on more than 30,000 cases in 1992-93). AR8057; AR8046. That level of exposure produced approximately 140 cases of vCJD. AR8046. At the height of Switzerland's BSE epidemic in 1995, the annual incidence rate of BSE was 73.6 cases per million adult cattle, but Switzerland has not identified a single case of vCJD. *See* Canada Report at 6-7. By comparison – and contrary to the district court's view adopted from R-CALF's erroneous calculations (*see infra* at 25) – Canada's incidence rate of BSE in 2004 is only ***0.3 cases*** per million adult cattle even if the case confirmed on January 11, 2005, is included in the 2004 incidence rate. *See id.* at 8, 30; *see also* Ferguson Dec. ¶ 8 ("[F]or the last 12-month period, Canada's OIE[8] incidence rate would approximate 0.36 cases per million head of cattle.").

Second, there is compelling scientific evidence that beef from Canadian cattle is safe for human consumption. Both Canada and the United States eliminate virtually 100% of the potential BSE infectivity from cattle slaughtered for human consumption by requiring the removal of the SRMs. These

---

[8] "OIE" is the acronym for Office International des Epizooties, or the World Organization for Animal Health.

practices effectively eliminate the potential for human exposure to vCJD through the consumption of beef. AR8089; *see also* Ferguson Dec. ¶ 13. In addition, a "substantial species barrier" is believed to protect humans exposed to BSE-contaminated tissue from contracting vCJD. AR8046. This explains why only approximately 150 cases of vCJD have been identified worldwide – 95% of which occurred in the United Kingdom – even though it is estimated that more than 1 million cattle were infected with BSE during the United Kingdom's epidemic. *Id.* The species barrier makes it "unlikely that there would be any measurable effects on human health from small amounts of infectivity entering the food chain." AR8089.

B. Canada Relies On Overlapping Risk Mitigation Measures To Protect The Public From Exposure To BSE

In identifying Canada as a minimal-risk country, USDA recognized that consumers of Canadian beef in the United States will be protected from exposure to the BSE agent by the risk mitigation measures that Canada has successfully implemented to protect its own consumers. *See, e.g.*, AR8051-53, AR8075. USDA distinguished the BSE epidemic in Europe in the 1990s, which was "an example of widespread exposure and establishment" of BSE, AR8057, to the discovery of a limited number of BSE cases in Canada, which had "[c]ontrol measures ... in place before the detection of the disease," *id.*, and "has taken ***every necessary step*** to prevent an epidemic," AR8098 (emphasis added). In addition,

consumers of Canadian cattle slaughtered in the United States are protected by the equivalent risk mitigation measures in place in the United States. AR8059-60; AR8070; AR8075.

In the late 1980s and early 1990s, Canada and the United States began to implement integrated risk mitigation measures in recognition of the growing BSE threat. *See* Canada Report at 42. Canada's science-based mitigation measures constitute a series of overlapping safeguards that, both alone and in conjunction with the equivalent United States controls, systematically limit the risks associated with BSE. AR8089-90; AR8098-99; *see also* Ferguson Dec. ¶ 6; Canada Report at 42-46 (table comparing measures). Canada's mitigation measures include the following:

1. Restrictions on imports from high-risk BSE countries, established 13 years before the first indigenous case of BSE was detected in Canada. In July 1989 and February 1990, respectively, the United States and Canada imposed a ban on imports of cattle from the United Kingdom and Ireland, where the incidence rate of BSE was skyrocketing in the absence of scientific understanding about how BSE was spread. AR8324; AR8051; Canada Report at 21. The import restrictions effectively halted the entry of BSE into both Canada and the United States from high-risk BSE countries. AR8051 (explaining that a low level of BSE may have infiltrated North America by 1990 through a small

number of cattle imported into Canada and the United States from the United Kingdom).[9]

2. *A ruminant-to-ruminant feed ban, implemented as a preemptive safeguard, limits recycling and prevents amplification of BSE.* Acting on the recommendation of the World Health Organization to control the "recycling" of BSE, Canada introduced a feed ban simultaneously with the United States in August 1997.[10] AR8096; AR8051; AR8075 (explaining that Canada's feed ban is even more protective than the United States' ban because it prohibits plate waste and poultry litter in ruminant feed). Canada's implementation of the ban, almost six years *before* it detected the first case of BSE in a Canadian cow in 2003, has been credited with dramatically reducing the exposure of BSE among Canadian animals, limiting the spread and preventing any amplification of BSE. AR8051-

---

9 *See also* Canadian Food Inspection Agency, Factsheet, "Overview of Canada's BSE Safeguards," at 2 (hereafter "CFIA Factsheet"), *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbfs2e.shtml (last viewed Apr. 13, 2005).

10 Of the small number of potentially BSE-infected animals that were imported into the United States and Canada before 1990, some may have been rendered and processed into animal feed, which in turn could have led to the development of additional cases (or the "recycling") of BSE. AR8051. Coordinated implementation of the feed bans by Canada and the United States was critical in preventing the unrecognized amplification of BSE. *Id.*

52; AR8098. Moreover, the feed bans in place in Canada and the United States eventually will eradicate the disease from the North American cattle herd. AR8099.

3. A national BSE surveillance program that exceeds OIE guidelines. Since 1992, Canada has surveyed the Canadian herd for high risk cattle showing clinical symptoms of BSE. AR8060 ("BSE surveillance and diagnostic capabilities in Canada" are "equivalent to and as effective as those in the United States"); AR8096; AR8098. Moreover, since 1996, Canada has exceeded the level of annual surveillance recommended by OIE. AR8099; AR8325. As a result of this intensive testing, since 2003, Canada has detected only three cases of BSE in Canada out of more than 43,000 high-risk animals surveyed (not including a fourth case detected in a Canadian-born cow in the United States). *See* CFIA Factsheet at 3-4; *see also generally* http://www.inspection.gc.ca (BSE surveillance). Further, Canada is in the second year of a five-year program to significantly broaden surveillance. AR8099; AR8053; AR8060; Canada Report at 28.

4. Slaughter practices that detect and eliminate potential BSE cases before they enter the human food system. Because the majority of Canadian cattle slaughtered for human consumption are between 18-22 months of age, and because the average incubation period of BSE is *at least* 4-5 years (48-60 months), AR8058, Canadian cattle taken to slaughter are not likely to have developed

infective levels of the disease. AR8096; AR8069; *see also* Ferguson Dec. ¶ 11 (scientific evidence suggests that the expected incubation period in Canadian cattle could be much longer than 4-5 years); AR8330 (even during the United Kingdom's epidemic, when BSE controls had not been fully implemented, only *0.01%* of cattle that developed BSE were less than 30 months of age); Canada Report at 15. This suggests that the Final Rule, based on a 30-month standard, is conservative. Further, when cattle are slaughtered in Canada and their meat exported to the United States, Canada's food safety measures provide additional protections to consumers. AR8075; AR8083; *see also* Canada Report at 9, 15.

5. The removal of SRMs to protect humans from BSE. Because of the effectiveness of Canada's overlapping network of BSE control measures, the vast majority of animals entering the human food system in Canada do not pose a risk of BSE. *See* Ferguson Dec. ¶ 6. Nevertheless, Canada (as well as the United States) implements a safeguard internationally recognized as the most effective way to protect consumers from exposure to the BSE agent: the removal of SRMs from all animals slaughtered for human consumption. *Id.*; *see also* AR8049 (the United States followed Canada's lead in banning SRMs). Removing SRMs ensures that, in the unlikely event that an infected animal enters the slaughter system during the period of infectivity when BSE is not clinically detectable, the

meat and meat products from the animal will be free of the tissues where BSE is concentrated. AR8049; AR8097-98; Canada Report at 10-11.

6. Epidemiological investigations to evaluate and respond to any suspected case of BSE. On the rare occasion that BSE has been detected in Canadian-born cattle, Canada has conducted an exhaustive epidemiological investigation to confirm the adequacy of its existing risk mitigation measures. AR8052-53; AR8061; AR8328. The rigor and transparency of Canada's post-detection investigations reflects yet another layer of protection in Canada's efforts to control BSE. AR8075; AR8099.[11]

C. USDA Correctly Found That Canada Poses A Low Risk Of Transmitting BSE Into The United States

Contrary to the district court's speculation that importation of Canadian cattle presents a "virtual certainty" that BSE-infected cattle will enter the United States (Opn., 2005 WL 525689, at *6), BSE has remained an exceedingly

---

[11] Canadian consumers have demonstrated that they are reassured about the safety of the beef supply in light of these BSE controls. *See* Canada Report at 17-18. Following confirmation of the two new cases of BSE in January 2005, Canadians have continued to consume Canadian beef at record levels. *See id.* at 18. It is telling that the district court cites no evidence to support its suggestion that the discovery of BSE in Canadian cows diminished the confidence of Canadian consumers and thus "triggered devastating losses" to the beef industry. *See* Opn., 2005 WL 525689, at *14 ("This was also the result in Canada with the discovery of BSE in Canadian cows.").

rare disease in the Canadian cattle population because of the success of the control measures outlined above. AR8096. The risk mitigation measures implemented on both sides of the border not only limit the potential spread of BSE, but ultimately will eradicate the disease. AR8099; *see also* Ferguson Dec. ¶ 6 (BSE controls used by Canada and the United States have "further reduced any risk associated with the imports"), ¶ 9 (explaining the errors in R-CALF's assessment of the risk that a BSE-infected animal would be imported from Canada into the United States).

II. CANADA'S DETECTION OF CASES CONFIRMED IN JANUARY 2005 DOES NOT PUT UNITED STATES CONSUMERS AT A GREATER RISK OF EXPOSURE TO BSE AND IS CONSISTENT WITH THE FINAL RULE

A. The Detection Of Two Cases Confirmed In January 2005 Does Not Mean That The Risk Of BSE Exposure From Canadian Beef Has Increased

Canada confirmed two new cases of BSE on January 2 and 11, 2005, respectively, bringing the number of cases detected by Canada's BSE surveillance program to three (not including a fourth case detected in a Canadian-born cow in the United States). *See* Opn., 2005 WL 5256899, at *3; *see also* Ferguson Dec. ¶ 7. The BSE case confirmed on January 2, 2005, was an 8-year old cow born in

October 1996, before Canada implemented its feed ban in August 1997.[12] The BSE case confirmed on January 11, 2005, was a cow born in March 1998 (age 6 years and 9 months) during the first year of Canada's feed ban.[13]

Importantly, and contrary to the district court's reasoning (Opn., 2005 WL 525689, at *6), the detection of the cases confirmed in January 2005 does *not* indicate that the risk of human or animal exposure to BSE in the United States has increased since the Final Rule was published. *See* 70 Fed. Reg. 18,252, 18,255-58. Because those cases involved cattle well over the age of 30 months (ages 70, 80, 81, and 98 months), *see* Canada Report at 29, none of these animals would have been permitted to enter the United States under the Final Rule. The current testing results from Canada's surveillance system reflect the past exposure of older Canadian cattle to the BSE agent, before the feed ban was fully implemented.

---

12 *See* CFIA Summary Report Case #2, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml, at 1-2 (last viewed Apr. 13, 2005); CFIA Questions and Answers Case #2, at 1-2, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2queste.shtml (last viewed Apr. 13, 2005).

13 *See* Canada Report at 15; *see also* CFIA Summary Report Case # 3, *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml (last viewed Apr. 13, 2005); CFIA Questions and Answers Case #3, at 1.

Moreover, Canada's risk mitigation measures operated in their normal course to exclude SRMs from the human food supply and bovine tissue from the bovine feed system. *See, e.g.*, CFIA Questions and Answers Case #3, at 1.

B. The Cases Confirmed In January 2005 Do Not Undermine USDA's Rationale For Listing Canada As A Minimal-Risk Region

The district court suggests the two cases confirmed in January 2005 highlight purported inadequacies in Canada's BSE surveillance program and undermine USDA's rationale in the Final Rule. *See* Opn., 2005 WL 525689, at *6. As explained below, however, these cases are fully consistent with USDA's science-based provisions in the Final Rule, which were developed to prevent any BSE infectivity from being introduced into the United States. *See* Ferguson Dec. ¶¶ 9, 11.

1. The Final Rule Contemplates The Discovery Of Additional Cases Of BSE In Canadian Cattle

The district court states that USDA attempted to "explain away" the discovery of the January 11, 2005 case of BSE, which involved a cow born within months after Canada implemented its feed ban. Opn., 2005 WL 525689, at *7. This fosters the misleading impression that the two cases confirmed in January 2005 (and particularly the case confirmed on January 11, 2005) were a surprise. While the timing of the cases may have been unforeseen, the potential for the

discovery of new cases was forecast by USDA when it stated that "it is possible there may be other asymptomatic BSE-infected animals in Canada." AR8099.

USDA acknowledged the potential for Canada to detect a "small" number of new cases of BSE, as Canada's risk mitigation measures operate to eliminate BSE from the Canadian national herd. AR8098; *see also* AR8100. Yet that small possibility, when considered in the context of the mitigation measures implemented by Canada and those imposed by the Final Rule, did not preclude USDA from listing Canada as a minimal-risk region:

> We concur that at present ***it is not possible to know with certainty whether any additional cows in Canada are infected with BSE***. However, ... we have concluded that the surveillance, prevention, and control measures implemented by Canada, in combination with the restrictions imposed by this rule, ***will comprehensively mitigate the risk of introducing BSE into the United States*** ....

AR8099 (emphasis added). As noted above, the two new cases of BSE involved animals well over 30 months of age that remain barred from the United States under the Rule. Every aspect of these new cases – their small number, the age of the animals, and their detection by Canada's surveillance regime – is fully consistent with USDA's scientific analysis in the Final Rule. *See id.* Indeed, USDA recently affirmed the Final Rule after exhaustively investigating the two cases of BSE confirmed in Canada in January 2005. 70 Fed. Reg. at 18,255-58 (citing information provided by Canada and cited herein). The district court's

suggestion that USDA improperly defended the Final Rule following Canada's confirmation of these cases in January 2005 (Opn., 2005 WL 525689, at *6) is therefore wholly without merit.

2. The Cases Confirmed In January 2005 Demonstrate That Canada's Surveillance Program Is Working And Results Confirm That Canada's Feed Ban Has Limited The Spread Of BSE

The detection of the two new cases of BSE demonstrates the successful operation of Canada's BSE surveillance program, which in turn confirms the effectiveness of Canada's feed ban.

First, the discovery of only three cases of BSE in Canada, out of 43,000 high-risk animals sampled by the Canadian Government since 2003, is "strong and reliable" evidence that "the mitigation measures ... are working and that prevalence is low." Ferguson Dec. ¶ 7; *see also* CFIA Factsheet at 3-4. Consistent with USDA's statements in the Final Rule (AR8098-99), the detection of these two cases suggests that Canada's surveillance program may detect a small number of additional cases as Canadian cattle reach the age where any BSE infectivity would manifest itself. *See* Canada Report at 30 (explaining *inter alia* that Canada's BSE testing program, which was significantly increased after May 2003, resulted in a more sensitive surveillance system "capable of detecting even more of the small number of possible BSE cases").

Second, the results from Canada's surveillance program demonstrate that Canada's feed ban has both effectively limited the BSE agent from being recycled and prevented its amplification in Canada's animal feed system. If the feed ban had allowed BSE to continue to spread through the animal feed system, the number of BSE-positive animals detected by Canada would be much higher. AR8331; *see also* Ferguson Dec. ¶ 7.

Even more telling than the small number of cases, however, is the older age of the four detected animals, ranging from 70-98 months. *See* CFIA Factsheet at 4 (distinguishing the risk of BSE infectivity in older versus young cattle). Current science indicates that larger doses of the BSE agent will shorten the incubation period, leading to the development of disease symptoms at an earlier age. AR8067; AR8096; AR8330-31. The fact that Canada's surveillance program has not detected BSE in younger Canadian cattle, at or anywhere near 30 months of age, provides further evidence that the feed ban has limited the BSE agent. AR8096; *see* Ferguson Dec. ¶ 10 (cases confirmed in January 2005 "indicate a limited exposure that occurred previously" and demonstrate that the transmission of BSE among cattle "has been significantly prevented through the implementation of a feed ban"), ¶ 9 (because "compliance with the feed ban continues to improve each year," "animals less than 30 months of age – *i.e.,* born after August 2002 –

would be far less likely to have been exposed to BSE"). This also suggests that the Rule, based on an under 30-month age limitation, is extremely cautious.

3. Canada's BSE Prevalence Rate Remains Well Below OIE's International Guideline For A Minimal-Risk Region

The district court determined *de novo* and without scientific basis that "[t]he discovery of four animals ... stricken with BSE [*i.e.*, three in Canada and a fourth of Canadian origin detected in the United States] ... is inconsistent with the USDA's assertion that the BSE incidence rate in Canada is 'very low' or 'minimal.'" Opn., 2005 WL 525689, at *6; *see also* R-CALF Br. at 13. The district court adopted the flawed estimate by R-CALF's declarant, Dr. Cox, that Canada's prevalence of BSE is "greater than 5.5 cases per million head of cattle," and thus exceeds the OIE's recommended guideline for a minimal risk region. Opn., 2005 WL 525689, at *6; *cf.* Ferguson Dec. ¶ 8 (explaining significant errors in Dr. Cox's analysis). These statements are completely at odds with the facts. Even considering the cases confirmed in January 2005, Canada's BSE incidence rate remains well within OIE's recommended guidelines.

USDA concluded that Canada's risk mitigation measures had prevented widespread exposure and establishment of BSE based on its comparison of Canada's annual incidence rate of two infected cattle in 2003 with the OIE-recommended level of "less than two infected cattle per million during each of the last four consecutive 12-month periods within the cattle population over 24 months

of age." AR8048. USDA correctly concluded that Canada's incidence rate, calculated by USDA as 0.4 cases per million head of adult cattle, was well below the OIE recommendation for incidence in minimal-risk regions. AR8096.

In recalculating the incidence rate in light of the cases confirmed in January 2005, even if the January 11, 2005 case were to be included in the 2004 test results, "the resulting incidence rate **(0.3 [per million head of cattle])** [correlating to two cases] would still be well ***below*** the two-in-a million threshold for a minimal risk country as defined by the OIE." Canada Report at 30 (emphasis added); *see also* Ferguson Dec. ¶ 8 (USDA similarly stating that "for the last 12-month[s], Canada's OIE incidence rate would approximate 0.36 cases per million head of cattle"). Because Canada expanded its surveillance program after May 2003, the detection of a few additional cases does *not* indicate that the prevalence of BSE in Canada is increasing, but rather that Canada is more capable of finding the small number of remaining BSE cases in the adult cattle population. AR8094; Canada Report at 30-31. Because Canada's incidence rate remains within OIE's recommended guidelines for a minimal risk region, USDA's rationale for listing Canada as a minimal-risk region on this basis applies with equal force today.

4. Canada's Feed Ban Continues To Provide An Effective Barrier To The Spread Of BSE, Consistent With OIE Guidelines

The district court questions the effectiveness of Canada's feed ban, even while recognizing that Canada's ban is virtually identical to the ban simultaneously implemented by the United States in response to the same risk factors. *See* Opn., 2005 WL 525689, at *8. The district court further states that USDA acted arbitrarily and capriciously in determining that Canada's feed ban was effective because the feed ban has now been in place for seven years and seven months, instead of the eight-year standard recommended by OIE. *See id.* at *7. These criticisms of the Final Rule are wrong.

First, the district court's suggestion that Canada's feed ban cannot be trusted to protect public and animal health in the United States is contradicted by the fact that the case confirmed on January 11, 2005 is the *only* BSE-infected animal ever identified in North America that was born after Canada and the United States implemented the feed bans. The Canadian Food Inspection Agency ("CFIA") determined that the infected animal may have consumed feed manufactured a short time after the Canadian feed ban was implemented, and that the feed may have been "cross-contaminated" by exposure to feed that contained

prohibited materials.[14] The district court assumes this determination was correct (Opn., 2005 WL 525689, at *13), yet also assumes that cattle that could be imported under the Final Rule, born ***five years or more*** after the feed ban was implemented, likewise may have been fed contaminated feed during their lifetime. The district court cites no evidence to support that wholly implausible assumption because there is none. *Cf.* Declaration of David Wilson (Head of the OIE's International Trade Department), No. CV-05-06-BLG-RFC, ¶ 7 (D. Mont. Feb. 24, 2005) ("a deficiency in the length of time a feed ban has been effectively applied could be addressed through restrictions on the age of live cattle imported," *i.e.*, through the extremely cautious 30-month age limitation in the Final Rule).

Given the level of complexity in implementing a national feed ban across a network of feed mills, retailers, rendering facilities, and farms, it was not possible for Canada or the United States to eliminate all prohibited animal feed the moment the bans took effect in August 1997, nor was it necessary to do so to achieve the ban's objective of limiting the spread of BSE in North America. *See*

---

[14] *See* "Report of the Investigation of the Third Case of Bovine Spongiform Encephalopathy (BSE) in Alberta, Canada," at 3 (Feb. 11, 2005), *available at* http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml (last viewed Apr. 13, 2005) (explaining that "this finding is consistent with the experience of all countries with BSE which have implemented feed bans"); *see also* Ferguson Dec. ¶ 10.

70 Fed. Reg. at 18,258; *see also* Canada Report at 34-35. The feed ban, as noted above, was implemented many years before the first case of BSE in North America was detected. There was a natural transition period following introduction of the ban, as sectors of the feed industry changed their practices to comply. *See* Canada Report at 34-35; *see also id.* at 39-40; Ferguson Dec. ¶ 11 (explaining that USDA's risk analysis took into account some lack of compliance with the feed ban in Canada, but that "even a feed ban that has not achieved 100% compliance would substantially limit further spread and amplification of BSE in the Canadian herd"), ¶ 14 (discussing assumptions of possible cross-contamination in the feed industry applied in USDA risk analysis). The evidence shows that Canada's feed ban has proven to be effective in limiting the spread of BSE.[15] AR8051-52; AR8060; AR8094; AR8339; *see also* Ferguson Dec. ¶¶ 9, 11.

---

[15] Following Canada's confirmation of two cases of BSE in January 2005, USDA and CFIA independently conducted investigations to assess the effectiveness of Canada's feed ban and feed ban inspection program. Both agencies concluded that Canada has a robust program, that overall compliance with the feed ban is high, and that the feed ban has proven effective. *See* CFIA's Feed Ban Review, at 3-4 (Mar. 2, 2005), *available at* http://www.inspection.gc.ca/english/anima/feebet/rumin/revexa/revintroe.shtml (last viewed Apr. 13, 2005); *see also* USDA's Assessment of the Canadian Feed Ban, at 1-3 (Feb. 25, 2005), *available at* http://www.aphis.usda.gov/lpa/issues/bse/bse.html (last viewed Apr. 13, 2005).

Second, Canada's feed ban, like that of the United States, satisfies the intent of OIE's recommendation by assuring an equivalent level of protection to a feed ban in place for eight years. AR8080. OIE established the eight-year recommendation when BSE was restricted to the United Kingdom and Europe, where thousands of cases of BSE had been detected *before* the countries introduced feed bans or other controls. AR8327. In the case of Canada, like the United States and other countries that introduced a preemptive feed ban, the number of animals infected with BSE when the ban was introduced would have been substantially less. Accordingly, the length of time required to reach the same low prevalence level of BSE as the countries (such as the United Kingdom) that introduced a feed ban after detecting actual BSE cases would be less than eight years. AR8054. As USDA correctly concluded, the duration of Canada's feed ban (currently seven year and seven months) addresses the expected BSE incubation period in North America, considering all actions Canada has taken to prevent the introduction and control the spread of BSE. AR8054-55; AR8080; *see also* Ferguson Dec. ¶ 11.

C. Canada's SRM Removal Policy And Feed Ban Represent The Most Effective Means Of Protecting Public And Animal Health

To support its finding that the USDA improperly relied on existing BSE control measures in its action in the Final Rule, the district court implies that neither Canada nor the United States should rely on feed bans or SRM removal to

prevent animals and humans, respectively, from being exposed to BSE. *See* Opn., 2005 WL 525689, at *7-8. The district court, like R-CALF, hypothesizes that BSE may spread among cattle through maternal transmission, blood, fetal bovine serum, saliva, rendered animal fat, poultry waste, and other routes. *See id.* at *7-9.

Contrary to the district court's speculation, however, the indisputable "primary source of BSE infection" is the ingestion of BSE-contaminated feed by cattle. AR8114. That practice has been prohibited on both sides of the border for many years. Extensive studies have failed to demonstrate that the BSE agent is present in the muscle tissue (AR9962) or blood of cattle (AR8086). Maternal transmission of BSE has not been proven, and "if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic." AR8099. In addition, the other routes of transmission suggested by the district court are either being controlled to the extent possible by BSE control measures in United States and Canada, or they are attenuated pathways of infectivity that have no conclusive scientific support. AR8086-88; AR8099.

More fundamentally, however, Canada's and the United States' feed ban and SRM-removal policy, along with other risk mitigation measures, provide the most effective barriers to BSE exposure from potential routes of transmission. AR8089-90; AR9965-66; Ferguson Dec. ¶ 12. Canada's mitigation measures, like those of the United States, provide comprehensive health protection to humans and

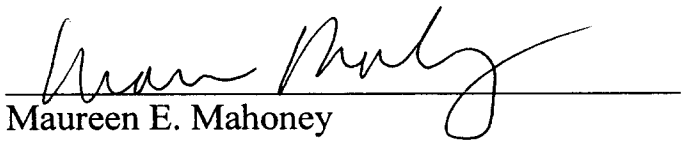
animals. AR8057; AR8095-96; AR8098-99. The district court's determination that the imports of Canadian cattle at issue here pose a threat to public and animal safety is based on speculative fears that have been thoroughly refuted by history, science, and the administrative record.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's order preliminarily enjoining the Final Rule.

DATED: April 14, 2005

Respectfully submitted,



Maureen E. Mahoney
Cassandra Sturkie
LATHAM & WATKINS LLP
555 Eleventh Street, N.W., Suite 1000
Washington, DC 20004-1304
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
Email: maureen.mahoney@lw.com
Email: cassandra.sturkie@lw.com

Counsel for the Government of Canada

CERTIFICATE OF COMPLIANCE

In accordance with Rule 32(a)(7) of the Federal Rules of Appellate Procedure, the undersigned certifies that the accompanying brief has been prepared using 14-point Times New Roman typeface, and is double-spaced (except for headings and footnotes).

The undersigned further certifies that the brief complies with the type-volume limitations set of Rule 32(a)(7)(B) and Rule 29(d). The brief is proportionally spaced, containing **6,997** words, exclusive of the table of contents, table of authorities, signature lines, and certificates of service and compliance.

DATED: April 14, 2005

Respectfully submitted,

Cassandra Sturkie

Cassandra Sturkie

CERTIFICATE OF SERVICE

Pursuant to Rule 31(b) of the Federal Rules of Appellate Procedure, I hereby certify that two (2) true copies of the document described as:

BRIEF *AMICUS CURIAE* OF THE GOVERNMENT OF CANADA IN SUPPORT OF APPELLANTS AND IN SUPPORT OF REVERSAL OF THE DISTRICT COURT ORDER GRANTING A PRELIMINARY INJUNCTION

were sent via Federal Express overnight mail (postage prepaid) and via electronic mail to the following:

A. Clifford Edwards
Taylor S. Cook
EDWARDS, FRICKLE,
ANNER-HUGHES & COOK
1601 Lewis Avenue, Suite 206
P.O. Box 20039
Billings, MT 59104
Telephone: (406) 256-8155
edwardslaw@edwardslawfirm.org
Counsel for Plaintiff/Appellee R-CALF

Russell S. Frye
FRYE LAW PLLC
3050 K Street, N.W., Suite 400
Washington, DC 20007-5108
Telephone: (202) 342-8878
rfrye@fryelaw.com
Counsel for Plaintiff/Appellee R-CALF

William L. Miller
THE WILLIAM MILLER GROUP, PLLC
3050 K Street, N.W., Fourth Floor
Washington, DC 20007
Telephone: (202) 342-8416
wmiller@radix.net
Counsel for Plaintiff/Appellee R-CALF

Lisa A. Olson
U.S. DEPARTMENT OF JUSTICE
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, N.W.,
Room 6118
Washington, DC 20001
Telephone: (202) 514-5633
Lisa.Olson@usdoj.gov
Counsel for Defendants/Appellants

Mark B. Stern
U.S. DEPARTMENT OF JUSTICE
Civil Division, Appellate Staff
RFK Main Building
950 Pennsylvania Ave., N.W.,
Room 7531
Washington, DC 20530
Telephone: (202) 514-5089
Mark.Stern@usdoj.gov
Counsel for Defendants/Appellants

Michael S. Raab
U.S. DEPARTMENT OF JUSTICE
Civil Division, Appellate Staff
RFK Main Building
950 Pennsylvania Ave., N.W.,
Room 7237
Washington, DC 20530
Telephone: (202) 514-5089
Michael.Raab@usdoj.gov
Counsel for Defendants/Appellants

Joshua Waldman
U.S. DEPARTMENT OF JUSTICE
Civil Division, Appellate Staff
RFK Main Building
950 Pennsylvania Ave., N.W.,
Room 7232
Washington, DC 20530-0001
Telephone: (202) 514-0236
Joshua.Waldman.usdoj.gov
Counsel for Defendants/Appellants

Victoria Francis
OFFICE OF THE U.S. ATTORNEY
2929 Third Avenue North
Suite 400
Billings, MT 59101
Telephone: (406) 675-6101
Victoria.Francis@usdoj.gov
Counsel for Defendants/Appellants

Philip C. Olsson
OLSSON, FRANK, AND WEEDA, P.C.
1400 Sixteenth Street, N.W.
Washington, DC 20036-2220
Telephone: (202) 518-6366
polsson@ofwlaw.com
Counsel for Proposed Intervenor/Appellant National Meat Association
(No. 05-35214)

John Walker Ross
Scott G. Gratton
BROWN LAW FIRM, P.C.
315 North 24th Street
Billings, MT 59102
Telephone: (406) 248-2611
jross@brownfirm.com
sgratton@brownfirm.com
Counsel for Proposed Intervenor/Appellant National Meat Association
(No. 05-35214)

Cassandra Sturkie

DATED: April 14, 2005
748497_10.DOC